K063346

510(k) Summary

APR 18 2007

Preparation Date: March 16, 2006

Applicant/Sponsor: Biomet Osteobiologics also known as EBI, L.P.
100 Interpace Parkway
Parsippany, NJ 07054
Establishment Registration Number: 1450662

Contact Person: Debra Bing
Director of Regulatory Affairs

Proprietary Name: Pro Osteon® 500R

Common Name: Bone Graft Substitute

Classification Name: Filler, Bone Void, Calcium Compound (888.3045)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

- Pro Osteon® 500R – K990131/K980817 (Interpore Cross International)
- Calcigen™ PSI – K032286 (Biomet Orthopedics)
- Marrow Plus (M+™) – K051695 (Berkeley Advanced Biomaterials, Inc.)
- PolyGraft™/TruBlock™ BGS – K040047 (OsteoBiologics, Inc.)
- MBCP™ - K043005/K051774 (Biomatlante)

Device Description: Pro Osteon® 500R Resorbable Bone Graft Substitute is an osteoconductive porous implant similar in structure to human cancellous bone. It is supplied sterile in various shapes and sizes.

When Pro Osteon® 500R is placed in direct contact with viable bone, the reticulated spaces in the implant are infiltrated with tissue. Bone formation occurs in apposition to the Pro Osteon® 500R surface and within the interstices of the implant skeleton. As the implant resorbs, bone and soft tissue grow into the space previously occupied by the implant.

Indications for Use: PRO OSTEON® 500R Resorbable Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. PRO OSTEON® 500R is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. PRO OSTEON® 500R can be combined with autogenous bone marrow aspirate, autogenous blood, and/or sterile fluids (saline or Ringer's solution). The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

Summary of Technologies: The technological characteristics (materials, design sizes, and indications) are similar to or identical to that of the predicate devices.

Non-Clinical Testing: Non-clinical laboratory testing was previously performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

Clinical Testing: None provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biomet
% Ms. Debra Bing
Director, Regulatory Affairs
100 Interspace Parkway
Parsippany, New Jersey 07054

APR 18 2007

Re: K063346
Trade/Device Name: Pro Osteon® 500R Bone Graft Substitute
Regulation Number: 21 CFR 888.3045
Regulation Name: Bone Void Filler, Calcium Compound
Regulatory Class: II
Product Code: MQV
Dated: April 3, 2007
Received: April 4, 2007

Dear Mrs. Bing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):_____

Device Name: PRO OSTEON® 500R

Indications For Use:

PRO OSTEON® 500R Resorbable Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. PRO OSTEON® 500R is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. PRO OSTEON® 500R can be combined with autogenous bone marrow aspirate, autogenous blood, and/or sterile fluids (saline or Ringer's solution). The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

Prescription Use ___X___ AND/OR Over-The-Counter Use __NO__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Mitchell

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063346